the analysis. 21 pts were still under treatment. Caregivers described these oral regimens as convenient (81%), well tolerated (84%) and with a good compliance by pts (76%).

Detailed analysis of the results by regimen (single-agent or combination) and line of treatment (1st or 2nd) will be presented during the meeting.

Conclusion: These data from every-day practice confirm, as shown in different clinical trials, that oral vinorelbine is an active and well tolerated chemotherapy for MBC, either as a first or second line in pts pretreated by anthracyclines and/or taxanes. The convenience of its oral administration associated with its good tolerance profile allows continuation of treatment until disease progression without a pre-planned maximum of cycles.

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Consistent progression-free survival benefit of capecitabine-bevacizumab in all prespecified subgroups of the RIBBON-1 study in patients with metastatic breast cancer (MBC)

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Background: RIBBON-1 was a randomised, placebo-controlled, phase III study of bevacizumab (A) or placebo (p) in two independently powered cohorts, receiving capecitabine (X) or taxane/anthracycline. Progression-free survival (PFS), the primary endpoint, was significantly greater with A combined with chemotherapy in both cohorts. Here, we report PFS sub-analyses based on prespecified subgroups of the X cohort.

Methods: Patients with HER2-negative MBC were randomised to X 1,000 mg/m^2 b.i.d. on Days 1−14 per 3-week cycle plus A or p. Subgroups analysed included: disease-free interval; number of metastatic sites; age; race; ECOG performance status; sites of involvement; disease measurability; size of target lesions; oestrogen receptor (ER) status; hormone receptor status; triple-negative status; prior therapy, and others.

Results: Baseline characteristics in the Xp control (n = 206) and XA (n = 409) arms were similar. Median PFS was 5.7 (Xp) and 8.6 (XA) months (stratified analysis hazard ratio [HR] 0.69, p = 0.0002). The XA combination improved the HR for PFS across all tested subgroups (table). The risk reduction was consistent with the significant benefit seen in the overall X cohort.

Conclusions: The XA combination was effective first-line therapy for HER2-negative MBC. XA provided clinical benefit to all tested patient subgroups.

Baseline risk factor [n]	Median PFS, months		HR [95% CI], unstratified analysis
	Xp	XA	
All patients [615]	5.7	8.6	0.67 [0.55–0.82]
ECOG performance status			
0 [324]	5.9	9.0	0.70 [0.53–0.92]
1 [288]	4.7	8.2	0.64 [0.48–0.84]
Age			
<50 [173]	4.5	8.0	0.51 [0.35–0.73]
⩾50 [442]	5.9	8.9	0.74 [0.59–0.93]
SLD of target lesions, cm			
<median 6.5 [262]	4.4	8.0	0.67 [0.50–0.89]
⩾median [239]	4.4	8.2	0.65 [0.47–0.88]
Hormone receptor			
positive [458]	6.2	9.2	0.69 [0.55–0.87]
negative [143]	4.2	6.1	0.70 [0.48–1.01]
ER/PgR/HER2-negative			
yes [137]	4.2	6.1	0.72 [0.49–1.06]
no [462]	6.1	9.2	0.68 [0.54–0.86]
Metastatic sites			
<3 [345]	6.4	10.2	0.63 [0.49–0.83]
⩾3 [270]	4.2	6.6	0.74 [0.55–0.98]
Visceral disease			
yes [423]	4.4	8.1	0.72 [0.57–0.90]
no [192]	6.2	10.6	0.58 [0.40–0.83]
Liver metastases only			
involved [24]	6.1	11.3	0.34 [0.12–0.93]
not involved [591]	5.5	8.5	0.69 [0.57–0.84]
Prior adjuvant chemotherapy			
yes [444]	4.4	8.3	0.64 [0.51–0.80]
no [171]	6.7	9.2	0.80 [0.54–1.18]
Prior anthracyclines			
yes [390]	4.4	8.3	0.64 [0.51–0.81]
no [225]	6.7	9.7	0.78 [0.55–1.09]
Prior taxanes			
yes [245]	4.2	8.7	0.62 [0.45–0.84]
no [370]	6.1	8.3	0.72 [0.56–0.92]

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PFS by patient subgroup for standard chemotherapies in combination with bevacizumab (BV) in the first-line treatment of HER2-negative locally recurrent (LR) or metastatic breast cancer (mBC): results from RIBBON-1

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Background: In two phase III trials (E2100 and AVADO), BV in combination with a taxane (T) as first-line therapy for mBC improved progression-free survival (PFS), compared with T alone. In RIBBON-1, combination of BV with standard first-line chemotherapy regimens also improved PFS in mBC patients (pts).

Methods: Pts were randomised 2:1 to BV plus chemotherapy vs placebo (PL) plus chemotherapy. Investigators could choose capecitabine (Cap) (2000 mg/m^2 x 14 d), T (nab-paclitaxel 260 mg/m^2 or docetaxel 75 or 100 mg/m^2), or anthracycline (Anth) (doxorubicin [A] or epirubicin [E] combinations: AC, EC, FAC or FEC-based chemotherapy, q3w). BV or PL were administered at 15 mg/kg, q3w. Key eligibility criteria were LR or mBC, no prior cytotoxic therapy for mBC, ECOG PS 0−1, HER2-negative disease and no CNS metastases. The primary endpoint was investigator-assessed PFS. The Cap cohort and pooled T/Anth cohorts were independently powered and analysed using a 2-sided stratified log-rank test (Cap: 80% power to detect HR = 0.75; T/Anth: 90% power to detect HR = 0.7).

Results: 1,237 pts (Cap=615; T=307; Anth=315) were enrolled. Combination with BV improved PFS (Cap cohort: PL 5.7 months (mo), BV 8.6 mo; p = 0.0002; T/Anth cohort: PL 8.0 mo, BV 9.2 mo; p < 0.0001). In prespecified subgroups, HRs favoured BV treatment arms.

	HR (95% CI)	
	Cap (n = 615)	T/Anth (n = 622)
All pts	0.67 (0.55–0.82)	0.66 (0.54–0.81)
Age, yr		
<65	0.67 (0.53–0.84)	0.63 (0.50–0.78)
⩾65	0.69 (0.47–1.02)	0.83 (0.52–1.34)
Triple negative		
Yes	0.72 (0.49–1.06)	0.78 (0.53–1.15)
No	0.68 (0.54–0.86)	0.61 (0.48–0.77)
No. of metastatic sites		
<3	0.63 (0.49–0.83)	0.65 (0.49–0.86)
⩾3	0.74 (0.55–0.98)	0.64 (0.48–0.85)
Bone-only disease		
Yes	0.47 (0.26–0.87)	0.39 (0.18–0.88)
No	0.70 (0.57–0.86)	0.72 (0.59–0.89)
Visceral involvement		
Yes	0.72 (0.57–0.90)	0.68 (0.54–0.86)
No	0.58 (0.40–0.83)	0.63 (0.42–0.94)
Disease-free interval		
<12 mo	0.81 (0.54–1.21)	0.62 (0.45–0.85)
⩾12 mo	0.63 (0.51–0.79)	0.69 (0.53–0.89)
Prior adjuvant chemotherapy		
Yes	0.64 (0.51–0.80)	0.67 (0.50–0.90)
No	0.80 (0.54–1.18)	0.64 (0.49–0.85)
Prior adjuvant T		
Yes	0.62 (0.45–0.84)	0.65 (0.39–1.07)
No	0.72 (0.56–0.92)	0.66 (0.53–0.83)

Conclusions: The overall treatment effect of combining BV with Cap, T, or Anth in RIBBON-1 is seen across the prespecified clinically relevant subgroups. Results are consistent with the findings of E2100 and AVADO and suggest that BV plus standard chemotherapies provides benefit to HER2-negative mBC pts with various clinical characteristics and disease histories.